Reid and Marguerite

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Sent: Monday, January 31, 2005 11:33 AM
Subject: docket no. 1980N-0208 (corrected copy)

January 29, 2005

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Division of Dockets Management
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Protecting Our Guardians
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Dear FDA and all others concerned,

I am writing to you during the 90 day comment period concerning the anthrax vaccine (docket no. 1980N-0208) because my husband has been forced to take the anthrax vaccines. After his third inoculation he suffered a bad reaction which took 3 months to clear up. A fourth shot would probably disable him permanently. He is a Tanker pilot in the AL Air National Guard and an Instructor Pilot in the Guard. He is a Major. He has been in the Guard for 19 years and has many honors and medals. He loves serving our country. He should not have to choose between the career that he loves and a gamble with his health. The anthrax vaccine license must be revoked before further harm is done to our military and our citizens.

The FDA must do more than a cursory review of the anthrax vaccine; it must protect military members and the public in general from this "adulterated" drug. Yes, according to Sammie Young, who was an FDA inspector for decades, the anthrax vaccine is an "adulterated drug." It is also "unusually hazardous" according to the Secretary of the Army, Louis Caldera, and the former Secretary of the Army, Togo West Jr. in 1992. The FDA must comply with the order of the Federal Judge, Honorable Emmet G. Sullivan. The ruling, on October 27, 2004, specifically states that the FDA must follow their own procedures and rules (see http://www.dcd.uscourts.gov/Opinions/2004/Sullivan/03-707c.pdf). When the FDA officials "review the labeling" of a vaccine the FDA goes through a "two-stage" process wherein 1.) an expert review panel analyzes the scientific data and 2.) submits a report to the FDA Commissioner before a proposed rule. The FDA is now taking a short-cut by not forming a new expert review panel to analyze the new data from the DoD and elsewhere. I have included some of the new data below which must be taken into consideration by a current expert review panel. The FDA is not adhering to its own requirements as it moves directly toward a proposed ruling for full anthrax vaccine licensure without a new review panel.

It is of vital importance to note that this 90 day public comment period does *not* truly fulfill the Judge's requirements because of the FDA's restrictions on the comments. The FDA clearly states, though it is buried in the 26 page notice, "FDA is not considering comments on the Panel's report in this proposed rule and proposed order," but rather comments "on FDA's responses to the Panel's report, not on the Panel's report directly" -- which concerned numerous bacterial vaccines, not just the anthrax vaccine. The FDA is taking comments on the actions taken in response to a 1985 expert panel, not the *current situation* and all the *new data of illness, injury and death* on a product that is *forced on 2.4 million people*. Nonetheless, the judge's injunction will hold "unless or until" the anthrax vaccine is proven to be safe and effective and until a 90 day period for public scrutiny is held under the FDA's Administrative Procedure Act; or until the anthrax vaccine is given to troops with their informed consent, meaning on a voluntary basis instead of a mandatory basis.

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1. The FDA notice about the 90 day comment period requires us to comment on how the FDA proceeded in response to the Dec 1985 expert panel's conclusions. The expert panel's report was called Bacterial Vaccine and Toxoids efficacy review document. According to Astrid Szeto, of FDA's CBER, the expert panel kept the anthrax vaccine in Category I (safe, effective, and not misbranded). In a rather disturbing decision by the FDA, Categories IIIA (products that would remain in market pending the completion of more studies) and IIIB (products for license revocation) were eliminated. All bacterial vaccines were to be reclassified in Categories I and II (unsafe, ineffective, and misbranded). The FDA also put *every other* bacterial vaccine into Category I unless the ***manufacturer requested*** that the license for its vaccine be revoked. *None* of these vaccines were placed in Category II from the information appearing in the FDA notice: "The FDA does not propose that any products be placed in Category II." More specifically, *every* bacterial vaccine for Michigan Department of Public Health, License No. 99, is listed as being revoked under the company name change to BioPort and license change to number 1260; yet, no update is given for the status of the anthrax adsorbed vaccine. One must assume it remains in Category I.

In critique of FDA's actions, a scientific study with long-term clinical trials should have been done before Cat. IIIA and IIIB products were put into Cat. I. That shows gross negligence on the part of the FDA and a disregard for its primary duty to protect the public from risky, even deadly, drugs. The FDA did not put any vaccines into Cat. II, which reveals that the manufacturers are of more concern to the FDA than the public safety. In removing Cat. IIIA and IIIB, and placing all remaining bacterial vaccines into Cat. I (unless the manufacturer chose to withdraw the license), the FDA failed to protect the public. It is difficult to believe that out of approximately 42 products, no further study was needed and no licenses were in danger of being revoked. For instance, the FDA notice reveals the fact that the FDA chose to ignore the expert panel's directive to put the Tetanus Antitoxin (for Massachusetts Public Health Biologic Laboratories, License No. 64) into Cat. IIIB; instead the FDA chose to place the Cat. IIIB product, Tetanus Antitoxin, into Cat. I with all the others. The reclassification of a product from having its license revoked to being considered safe and effective illustrates gross negligence on the part of the FDA; and it proves the point that at the very least more testing should have been done before a "shell game" began.

2. The FDA also withdrew a labeling section called "Overdosage" from many bacterial vaccines. Such an action does not take into consideration the cumulative toxic effects of mercury, aluminum, benzethonium chloride, formaldehyde, and other components. Such action is also negligent in not anticipating the possibility of an allergic reaction to repeated doses of a vaccine. The 1985 expert review panel found disparities in the dosage requirements. The expert panel said it should be only 3 inoculations, rather than the 6 shot series given now. The FDA's notice addresses this by claiming it was the same number of shots in the same 18 month time frame, but the wording is not clear. This inconsistency in the dosage requirements is one example of a change made between the anthrax vaccine that was supposedly studied and the vaccine that was actually licensed. In summary, the anthrax vaccine product labeling should include an "Overdosage" section that addresses these vital points.

3. Moreover, the FDA did not offer the contents of the report from the Committee to Assess the Safety and Efficacy of the Anthrax Vaccine, called "The Anthrax Vaccine: Is it Safe? Does it Work?," for public scrutiny -- although it lists other letters and reports in great detail.

4. The FDA also failed to address the problem with the anthrax vaccine license. The anthrax vaccine that was originally licensed is not the one that is currently used today under that same license. The current anthrax vaccine is from a different strain of anthrax, made from different manufacturing processes, and has a different formula from the old one. These unapproved alterations of the anthrax vaccine were reported to the FDA in a Citizen Petition filed on Oct. 15, 2001 (Docket: 01P-0471 Issue the NFR Placement of Anthrax Vaccine as Category II). The FDA took approximately a year to respond to the Petition and did not hold the DoD or BioPort accountable for their illegal actions. This is unacceptable! The FDA must do its job, instead of waiting for the courts to settle the matter. The Citizen Petition was also sent to the General Accounting Office which confirmed the concerns in a report of its own (http://www.gao.gov/new.items/d02181t.pdf). The GAO has estimated that adverse reactions to the anthrax vaccine are 100 times higher than what the DoD first claimed. In Anthrax: a deadly shot in the dark, Ret. Lt. Col. Thomas S. Heemstra writes "The original vaccine's license is being illegally used for the second vaccine. The General Accounting Office (GAO) confirms in a report dated April 29, 1999, Medical Readiness: Safety and Efficacy of the Anthrax Vaccine, that "the anthrax vaccine being administered by the Defense Department is not the same as the one originally tested prior to 1970." Furthermore, no safety testing has been done on the two anthrax vaccines after all this time, according to Kwai Chan testifying for the GAO in a House Government Reform Committee hearing on May 7, 1999. Therefore, a new study needs to be done and perhaps a new license issued on this very different vaccine. No more short-cuts.

5. The FDA notice lists the Brachman study as evidence of the anthrax vaccine's effectiveness. However this data is from the 1950s and 60s, rather than 21st century science. As stated above, it is also from a *different* version (the current vaccine is even from a different strain of anthrax) of the anthrax vaccine; the FDA notice states "The Brachman study

used an earlier version of the protective antigen-based anthrax vaccine...."

Further, Brachman's field trial was an unscientific and vague study. Several reports were published in 2004 by Dr. Walter R. Schumm of Kansas State University, et al. that prove the 1962 Brachman study was incorrect! The reports include "A statistical reanalysis of Brachman et al.'s 1962 study of a human anthrax vaccine," "How 'adequate and well-controlled' was the 'clinical trial' of a human anthrax vaccine, 1955-1959?," and "Anthrax vaccine and Gulf War illness symptoms in Captain Jean Tanner's Dover Air Force Base survey." The Abstract for "A statistical reanalysis..." states,

> In late 2003, the Brachman et al. (1960, 1962) field study of an earlier anthrax vaccine became the basis for an FDA regulatory determination that the currently licensed vaccine was effective against B. anthracis strains, regardless of the route of exposure. Here the Brachman et al. (1962) field study is reexamined statistically, analyzing the vaccine's effectiveness as a function of risk levels, levels of vaccination status, types of anthrax infection, mill locations, and two study components (total versus experimental groups). Fisher's exact tests were used to compare the vaccine and non-vaccine groups because Fisher's Exact Tests are more accurate than the traditional chi-square tests, especially when cell sizes or probabilities are small. *Numerous limitations of the trial were discovered or reaffirmed.* Even taking both cutaneous and inhalation anthrax into account, we found that the vaccine's protective effects were not statistically significant ($p<0.05$) in 75% of the mills studied. We found *no evidence for the effectiveness* of incomplete vaccinations, although design or reporting flaws in the original study mitigated against finding such evidence. The reanalysis of Brachman et al. (1962) does indicate that the anthrax vaccine may help provide some *marginal protection against cutaneous anthrax* infection; however, cutaneous anthrax is seldom fatal and usually easily cured with antibiotics. *The data do not provide statistically significant evidence of protection against inhalation anthrax.* In conclusion, our reanalysis indicates that Brachman et al.'s (1962) data actually fell far short, as had actually been long acknowledged by leading anthrax experts until some time after 1999, of demonstrating the efficacy of the anthrax vaccine in humans, especially with respect to inhalational anthrax infection. [italics mine]

Dr. Schumm's study reveals that the Brachman field study is not a sound foundation for concluding that the anthrax vaccine is effective against either cutaneous or inhalation anthrax. At the very least, more study is in needed using modern scientific techniques.

Dr. Schumm also reveals pertinent information on the safety of the anthrax vaccine. In his report "Anthrax vaccine and Gulf War illness...," the Abstract states,

> Air Force Captain Jean Tanner surveyed 252 members of her unit at Dover Air Force Base in 2000 to attempt to study the unusual symptoms being reported by a large number of her unit members, symptoms she believed to be related to their anthrax vaccinations.... nearly *nineteen percent* of the unit would have been classified as having Gulf War illness by the CDC definition.... *The results cast doubt on the safety of at least the lots of anthrax vaccine that were used at Dover Air Force Base at that time.*" [italics mine]

Dr. schumm's study indicates that at least 19% of the military members interviewed were seriously ill from the anthrax vaccine. The FDA must launch an investigation, using this current data with a new expert panel, into this unacceptable level of adverse reactions. The anthrax vaccine appears to be undermining military readiness and national security. More importantly, individuals who wanted to "be all that [they] can be" are now unable to much of anything due to poor health.

The Brachman study leaves room for many unanswered questions. Let's find the answers to those questions. For instance, exactly when did the study begin and end? It only included 1249 people, which cannot substantiate a vaccination program for 2.4 million people. Of the 116 who received incomplete inoculations of either vaccine or placebo, how many vaccines did each one receive? As far as the 340 who received no treatment, were they from the 379 who received anthrax vaccine, the 414 who received placebo, or the 116 people in combination with members from the other group/s? Exactly how many of the mill workers had the full series of the anthrax vaccine? What were the long-term effects? No studies have been done on the long-term effects! According to Kathryn Zoon, head of the FDA's Center for Biologics Evaluation and Research, in a May 1998 letter that data on long-term effects for this vaccine have never been submitted to the FDA." This Brachman study data tells us nothing. When will the FDA demand a thorough clinical study from an unbiased, well-qualified, party on the anthrax vaccine's safety, effectiveness in protection against inhaled and cutaneous anthrax, and the vaccine's long-term effects?

In Brachman's study did the observational group for inhalation anthrax receive placebo or the vaccine or both? In the group with cutaneous anthrax, three people had two or three injections of the anthrax vaccine and still contracted anthrax. Therefore the vaccine does *not* offer an effective means of protection against cutaneous exposure. In *four* mills, *only 5 cases* of inhalation anthrax occurred and *only 21 cases* of cutaneous anthrax. These numbers are too small to support the

efficacy of the anthrax vaccine. In the words of the FDA notice "FDA agrees that the five cases of inhalation anthrax reported in the course of the Brachman study are too few to support an independent statistical analysis."

The FDA goes on to write that because no cases of inhalation anthrax occurred in the vaccinated group -- only the five from the placebo group and observational groups -- the route of exposure does not need to be specified on the product label. This is sound science? The FDA is ignoring the fact that 3 people who had received vaccine injections did contract anthrax cutaneously. Obviously the route of exposure is important. The FDA must admit the heavy anthrax spores may have simply fallen to the floor in the mills and kept people from contracting inhalation anthrax by the law of gravity not the vaccine. Basic science asserts that in order to protect against an airborne biological attack, the vaccine needs to be inhaled, not injected. The FDA needs to do a study to see if enough antibodies accumulate in the alveoli air sacks of the lungs to prevent an infection from setting in when anthrax is inhaled. The lungs are vulnerable to attack because they do not have as much of a blood supply compared to other parts of the body, and hence not as many antibodies on the scene of an attack. According to the Virtual Flight Surgeons "A second area of concern is the lack of robust research in demonstrating the effectiveness of the vaccine in preventing the inhalation form of anthrax... Studies in guinea pigs and mice have not shown high rates of protection offered by the vaccine" (http://www.aviationmedicine.com/anthrax.htm). More specifically, Dr. Meryl Mass stated that "Of 33 anthrax strains studied, 27 killed *at least* 50% of guinea pigs that had received the human anthrax vaccine" (http://www.dallasnw.quik.com/cyberella/Anthrax/DoD_answ.html). A 1985 interim ruling from the FDA stated there is not enough data to claim inhalation protection against anthrax. The FDA's original 1985 review of the anthrax vaccine, published in the Federal Register, reads: "Anthrax vaccine poses no serious special problems other than the fact that its efficacy against inhalation anthrax is not well documented." However, the vaccine is currently being misused against inhalation anthrax by the DoD.

In an article called "Scientist challenges effectiveness of Pentagon's anthrax vaccine" in The Birmingham News on July 18, 2000, written by Thomas E. Ricks of The Washington Post, Dr. George A. Robertson, a molecular biologist who specializes in pharmaceuticals and a biological warfare expert, revealed that the anthrax vaccine does not offer full immunity to anthrax. Dr. Robertson explained that "the monkeys sickened even though they had been given significantly larger doses of vaccine than humans receive, relative to their weight." Thus the article postulates, inoculated soldiers would be sick and unable to fight after anthrax exposure.

Even the Secretary of the Army, Louis Caldera, wrote in a memorandum in September 1998 that the anthrax vaccine "involves *unusually hazardous risks associated with the potential for adverse reactions* in some recipients and the possibility that *the desired immunological effect will not be obtained* by all recipients." The manufacturer, BioPort, also made such claims in its request for indemnity in its contract with the DOD.

6. The FDA needs to have a study that is pertinent to the current terrorist situation. Scientists can easily create virulent strains of weaponized anthrax or anthrax that has been genetically altered. The study needs to be done with anthrax that has been milled into a powder. The study should cover all the 60-some-odd known strains of anthrax. The FDA must not give a license for an anthrax vaccine, a mandatory product for the military, based on a study with a weak, naturally occurring anthrax strain from goat hides in the 1950s and 60s. The FDA notice claims that the anthrax vaccine protects against *all* types of anthrax, but this is *impossible* given so many different strains of naturally occurring anthrax and the possibility of new strains being scientifically developed by combining these anthrax strains in various ways. Kwai Chan, Director, Special Studies and Evaluations, said "These studies [by the DoD in the 1980s] found that the licensed vaccine protected against some but not all strains of anthrax." in a hearing before the National Security, Veterans Affairs, and International Relations Subcommittee on Government Reform (http://www.gao.gov/AIndexF499/abstracts/ns99148t.htm). It is also important to note that the 1985 expert review panel could not possibly have imagined that the anthrax vaccine would be used on a large scale against inhaled anthrax. According to page 30, footnote 9 of Judge Sullivan's ruling, the attorney for the DOD and FDA said "But it's absolutely right, Your Honor, that the possibility of weaponized anthrax was not in the minds of the advisory panel and probably not in the minds of the FDA." May I repeat: a new expert panel that can assess the *current situation* and the *latest data* must be formed to examine whether or not to allow a license for the anthrax vaccine.

7. The FDA is to be commended for updating the anthrax vaccine label/product insert in 2002. The label revision shows the systemic adverse reaction rate to be 5 - 35%. That is 120,000 to 840,000 people with serious reactions such as heart problems and heart attacks, arthritis, auto-immune diseases (Lupus, MS, Guillain Barre Syndrome, Lou Gehrig's disease), seizures, memory problems, migraines, and so on. The anthrax vaccine package insert also cites 6 deaths that have been directly linked to the product. To look at the insert go to www.bioport.com. Even an employee of BioPort (the manufacturer), Richard Dunn, died from severe inflammation due to the anthrax vaccine according to the Medical Examiner (http://www.whale.to/v/dunn.html). At 17 years old, Tyran Duncan of TN, was paralyzed with GBS after the anthrax vaccines. In Feb. of 2003, doctors at Walter Reed Army Medical Center wrote "We have recently encountered numerous service members who have precipitation and exacerbation of headache syndromes with concomitant receipt of the anthrax vaccine. The immunopathogenic mechanism has yet to be

established" (http://www.delawareonline.com/newsjournal/local/2004/10/10exdafbcommander.html). There are thousands who are disabled now, account after account in the news, yet the FDA has not revoked the anthrax vaccine's license in the face of this new information.

8. When squalene, an *illegal* adjuvant, was found in parts per billion testing in eight out of eight anthrax vaccine lots the FDA did not revoke the license and no investigation was done. Please see Congressman Metcalf's Report from March 1999 (GAO/NSIAD-99-5) for more on this or go to http://home.att.net/~dstormmom/metcalf.htm.

9. When Bioport failed 4 FDA inspections and had 18 violations, the FDA temporarily shut down the plant but didn't revoke the anthrax vaccine's license. The FDA's notice reads "FDA believes that the routine inspection of licensed facilities adequately assures that the information held in product licenses is current and that a routine review of safety and efficacy data is *unnecessary* and *burdensome*." Though burdensome, it is necessary, as in the case of the Bioport debacle. What is the inspection schedule for Bioport? Is every lot being checked for squalene in p.p.b.? The FDA must ensure the safety of this product or revoke the license.

10. The FDA must not give a license when the anthrax vaccine, as shown by the Panel report in 3. Analysis--, "has not been employed in a controlled field trial." No controlled field trial -- this is unacceptable in a licensed vaccine, and particularly irresponsible in a mandatory vaccine. As far as getting volunteers is concerned, if 8,000 people will volunteer for an AIDS vaccine trial (AIDS UPDATE 2001 by Gerald J. Stine, Ph.D. p.309) for a mere $1,200. each (www.hivresearch.org/opportunities/clinical_trials/vcrc.html), then certainly some will participate in an anthrax vaccine trial.

11. The FDA is guilty of letting the DoD do its job for it: "FDA has reviewed the historical development of AVA and concluded that DoD's continuous involvement with, and intimate knowledge of, the formulation and manufacturing processes of all of these versions of the anthrax vaccine provide a foundation for a determination that the MDPH anthrax vaccine is comparable to the original DoD vaccine." Basically the FDA trusts that the DoD knows what it is doing with this vaccine. Is the DoD a Health Dept in any way, shape, or form? The FDA appears to leave the problem-child/anthrax vaccine in the DoD's capable hands because they don't want to deal with it. It is called "passing the buck." There is absolutely no scientific data to support the FDA's naive conclusion here.

12. FDA's CBER has "a strategic goal of assuring a high quality research program." How can the FDA hope to maintain its high standing in research for biologics or any other area when it gives out a license that has a dearth of testing and concrete data behind it and/or ignores the negative side-effects of a product once it is in use -- as in the case of the anthrax vaccine. Furthermore the FDA notice states: "Through cooperation with international, other Federal, and State health care agencies and the industry and academia, the agency intends that its research resources will reap the benefits of a wide range of experience, expertise, and energy from the greater scientific community while the agency maintains its legal and regulatory obligations." In taking this path, the FDA runs the risk of losing its objectivity and credibility when it becomes entangled in deals and collaborations with other organizations, like the DoD, which often have certain agendas of their own. Currently, the FDA is also in danger of being swayed by lobbyists. According to an article in JAMA, "Postmarketing Surveillance -- Lack of Vigilance, Lack of Trust," in the fiscal year 2003, the FDA received $4.9 million in lobbying money from pharmaceutical companies. Between 1993 and 2001, the FDA received approximately $825 million in "user fees" from drug and biologic manufacturers (http://jama.ama-assn.org/cgi/content/full/292/21/2647). Another article, in Nature by Meredith Wadman, called "Fear of bias puts spotlight on drug approval," reveals that "33% of the voting members [in committees for drug approvals] had admitted a financial stake in the outcome." This is very disturbing. In the words of Congressman Dan Burton, "We have to be absolutely sure that there are no conflicts of interest in the drug-approval process. If the American people thought that there was even a possibility that the drugs approved by the FDA made it to market because some doctor or scientist had a financial stake in the products, then they would lose confidence in the entire system." (http://www.nature.com/cgi-taf/DynaPage.taf?file)

13. The FDA followed the expert panel's advice for setting up compensation to those injured, which was reasonable and just. However, the FDA has fallen short of the goal since (NVICP) the National Vaccine Injury Compensation Program is only for children, not adults. Childhood vaccinations are not the only broadly administered vaccines. Our military members deserve a similar program when a bad product such as the mandatory anthrax vaccine causes injury, disability, or untimely death. As the FDA may be aware, BioPort has indemnity; and, it is difficult for military members to seek justice in the courts due to the Feres Doctrine. Thus, when it comes to military members wrongfully harmed by the anthrax vaccine, no one is accountable. The checks and balances of our governmental branches have thus far failed to save military service members. Therefore, it is time for the FDA to take responsibility as the institution which will protect our military members from further negligence and harm. It is the FDA's duty to protect the public from dangerous products such as the improperly and "illegally" licensed, and "unusually hazardous," anthrax vaccine.

14. The FDA notice claims to welcome "comments on how appropriate informed consent and protection of human